EXPEDITED PROCEDURE EXAMINING GROUP: 3626

Docket: 6944

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Badri N. Prasad		
Appln. No.:	09/733,215	Confirmation No.	3483
Filing Date:	December 8, 2000	Examiner:	N. Pass
Title:	**Method for High-Risk Member Identification**	Group Art Unit:	3626

DECLARATION UNDER 37 C.F.R. § 1.132

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I, **Gerald L. Lutgen**, having a residence at 1434 Kenneth Street, St. Paul, MN 55116, and being a U.S. citizen, hereby declare as follows:

1. I am a co-inventor of the above-identified application.

2. I have a Bachelor's degree in Sociology/Research Methods and a Master of Science degree in Health Informatics/Applied Statistics from the University of Minnesota.

3. I have worked in the field of Health Informatics and Applied Statistics for 35 years. I have extensive experience in the application of health informatics and applied statistics to a broad range of health care problems and opportunities. I have worked both as an applied information scientist and an executive in this field.

In 2005, I founded Applied HealthWorks, a company whose mission is to apply advanced health informatics methods in the pursuit of solutions to health issues affecting the lives of millions of people. I design, develop and distribute products to the health and fitness consumer markets. I also provide consulting services in this field.

Prior to 2005, I was employed by UnitedHealth Group, a leading health and well-being services provider. While at UnitedHealth, I lead the development of health intelligence tools that enabled the National Health Service of England to implement a care management process for high-risk patients. I was also a member of the team that founded Ingenix, a subsidiary of UnitedHealth whose mission is to transform organizations and improve health care through information and technology and to improve the affordability, quality, usability, and accessibility of health care. I participated in and managed various product research and development initiatives for Ingenix.

Prior to my employment at UnitedHealth, I was responsible for human sensory testing, statistics and technical computing laboratories in consumer foods research and development at the Pillsbury Company. I also held a variety of technical and analytics positions relating to the management of large-scale health-related clinical trials at Medtronic, Inc.

4. I have read and understand the subject patent application and have also reviewed the pending claims in this application.

5. I am familiar with the Final Office Action mailed on February 27, 2008, wherein:

(i) Claims 1-11 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Published Application No. 2001/0020229 ("Lash") in view of U.S. Patent No. 6,385,589 ("Trusheim") and Canadian Published Application No. 2,216,681 ("Boyko");

(ii) Claims 12-13 were rejected under 35 U.S.C. § 103(a) as unpatentable over Lash, Trusheim, Boyko as applied to claim 1, and further in view of U.S. Published Application No. 2003/0167189A1 ("Lutgen"); and

(iii) Claims 14-15 were rejected under 35 U.S.C. § 103(a) as unpatentable over Lash, Trusheim, Boyko as applied to claim 1, and further in view of Lutgen and U.S. Patent No. 5,845,254 ("Lockwood").

6. I have reviewed the prior art references of Lash, Boyko, Trusheim, Lutgen and Lockwood cited in the § 103(a) rejections in the Final Office Action mailed February 27, 2008.

7. The Lash and Boyko prior art references teach one of ordinary skill in the art how to create a predictive model that identifies high-cost or high risk patients from a homogeneous group of patients all having the same disease or health condition.

8. The information contained in Lash and Boyko, either individually or read in combination, does not provide sufficient information or teaching to enable one of skill in the art to create a single predictive equation that can generate predicted future healthcare utilization scores for a population of members irrespective of the members' diseases of health-related conditions described in claims 34-50 of the present application.

9. The systemic, multiple-disease approach to predictive modeling of healthcare utilization that is needed to generate the predicted future healthcare utilization scores recited in claims 34-50 of the present application has fundamental differences from the predictive models that are described in Lash and Boyko. Lash and Boyko model very different populations than those modeled by the methods and system respectively described in independent claims 34, 42, and 43. While the present invention is designed to work with an entire population of members, such as an entire population of members covered by a health plan, the Lash and Boyko models are designed to work only with subsets of such a population. Additionally, the present invention employs variables that account for risk for any number or combination of diseases and health conditions that may interact through co-morbidities and complications.

10. The process of developing a meaningful predictive risk model for members of a population with any number and combination of diseases and health conditions was neither a trivial nor an obvious modification of a single disease predictive model, such as described in Lash and Boyko. The creation of such a predictive model required the invention of a novel approach and methodology for predictive modeling and intervention analysis. Such a novel approach is reflected in the present application and was undertaken by the inventors of the present application to enable the provision of care coordination services to high risk patients.

To achieve the present invention, the inventors first concluded that previously defined single disease at-a-time management systems, such as the Lash and Boyko models, did not constitute an acceptable starting point for this work. They simply did not teach how to deal with the primary care coordination challenge – that the system had to work efficiently across a comprehensive structure of diseases where the persons under evaluation by the system could have any number of diseases or health-related conditions (including none), and that the diseases and health-related conditions could involve any number of organ systems. The single-disease models such as Lash and Boyko also did not deal effectively with the fact that candidates would typically be taking a very large number of drugs with unclear interactions and be under the care of multiple, uncoordinated medical specialties. In fact, the single-disease systems typically assumed the opposite - that patients were on a closely managed drug regimen, managed by the appropriate medical specialty. These single-disease systems also did not offer the kind complex multi-disease intervention and risk factor structures appropriate to the challenge.

Therefore a new approach was required. The first order of business was to create a predictive model that placed individuals with any number of diseases onto a continuum of risk where risk could be meaningfully ranked across its entire continuum. This work is described in

detail in co-pending patent application Serial No. 09/635,911, which is incorporated by reference in the present application on page 6 of the specification. It shows how to develop a predictive equation based on an episode grouper, such as described in U.S. Patent No. 5,835,897, combined with selected powerful utilization variables (such as the number of medical specialist treating the patient). The episode grouper functions to classify very nearly all of a persons medical and pharmacy claims history into a comprehensive disease structure that accounts for co-morbidities and complications. Once the episode grouper and utilization variables were developed, statistical modeling studies were performed across complex multi-million member data bases into order to find the optimal structure of variables and weight for the predictive equation utilized to generated the utilization scores recited in claims 34-50 of the present application.

It also become apparent that basing selection of intervention members only on the risk score provided by the model would provide an incomplete criteria for identifying intervention members for a care coordination program. Simply stated, we concluded that the method should select those individuals that would profit most from intervention by a care coordination program. To accomplish this, we invented an efficient and effective structure of intervention flags and risk factors that worked in the context of persons with any number of diseases, a large number of drugs and potentially uncoordinated treatment through multiple medical specialties. In other words, the intervention flags and risk factors are defined to enable identification of intervention members irrespective of the members' particular diseases or health-related conditions, drugs, co-morbidities, and complications.

Again, the teachings of the one disease at-a-time systems such as Lash and Boyko were not helpful in achieving this efficient and effective structure of intervention flags and risk factors. It is difficult to develop and maintain a satisfactory body of rules defining intervention

flags and risk factors for even a few major diseases. It becomes unmanageable when this is attempted for a comprehensive structure of diseases. Most available systems for classifying diseases define from a few hundred up to thousands of individual diseases. In our instance, individuals could have any number of diseases taken from an episode grouper based disease structure containing about 450 classified diseases. For this reason, a rule-based approach such as that taught in the Trusheim reference was also entirely unworkable.

Therefore, we invented a structure of intervention and risk factors that are efficient and meaningful across a comprehensive structure of diseases. For example, being wheel chair bound or being blind may have care consequences for the care of many diseases, even though the cause for being blind or wheel chair bound may no longer be operative in a chronic disease sense. Therefore, the definition and selection of intervention criteria for patients with different diseases and conditions and combinations thereof required a substantially different and more complex analysis than are needed to identify intervention criteria for a single disease.

The final step was to ensure that each of these major system components, predictive model, intervention and risk factors did in fact work efficiently and effectively to enable the identification of intervention members from a population of patients irrespective of the members' diseases, health-related conditions or lack thereof. Implementation details of the system and method went though significant modifications as a result of our large-scale real-world testing. Overally, the development of the present invention as described in claims 34-50 required multiple person years of effort.

11. The Lash prior reference does not teach or suggest to one of ordinary skill in the art the system and methods described in claims 34-50. A reading of Lash only informs one of

skill in the art that the development of a risk prediction model for more than one disease or condition would be difficult.

12. The Boyko reference does not teach or suggest to one of ordinary skill in the art the system and methods described in claims 34-50. Boyko teaches one of ordinary skill in the art about a system in which intervention candidates with a high likelihood of an adverse event are identified from a group of patients having the same disease or condition. While Boyko also suggests in general terms the use of multiple single-disease risk outputs to develop a "risk factor" for each patient by viewing "each disease or condition as a module which can be cross-referenced like the fields of a relational database," this description is insufficient to enable one of ordinary skill in the art to calculate the predicted future healthcare utilization for members having an combination of diseases or health conditions required in claims 34-50. That is, Boyko does not teach or suggest a method for combining multiple, single-disease risk outputs into a score that places all persons irrespective of their diseases on a single numerical scale that allows ranking and comparison of persons along a meaningful measure of risk.

13. The Trusheim prior art reference teaches one of ordinary skill in the art about a system in which intervention candidates with multiple diseases or conditions are identified based upon matching information in their medical claim data with pre-defined criteria or rules. This method of identifying intervention candidates is fundamentally different from the disease-based predictive model risk assessment methodologies described in the Lash and Boyko references. The Trusheim approach is also difficult to implement on a large scale because the number of intervention rules quickly becomes very large and consequently difficult to implement and maintain. Also, as in Boyko, Trusheim does not teach or suggest a method for combining the information about multiple sources of risk in to a single numerical risk score.

14. It would have been illogical to one of ordinary skill in the art, as of December 8, 2000, to combine the Lash, Boyko and Trusheim teachings as asserted by the Examiner because, read collectively, the references would teach one of skill in the art to take one of two approaches, both of which teach away from the present invention as recited in claims 34-50. The asserted combination of references read together would teach either (1) that one must start by modeling risk only for a homogeneous population or (2) that one should develop a multi-disease approach by making a qualitative, not quantitative, combination of risks associated with multiple diseases and conditions. Both approaches yield unwieldy and ineffective systems for selecting intervention patients from a population of members having an number of combinations of diseases or health-related conditions, as well as co-morbidities and complications. Thus, the present invention described in claims 34-50 is not an obvious combination of the prior art references of record.

15. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the instant application or any patent issuing thereon.

Dated: June 26, 2008 By: Gerald L. Lutgen

Gerald L. Lutgen